UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

JOHN C. BREITENBACH, JR., as Administrator
of the ESTATE OF DEBORAH J. BREITENBACH,

Plaintiff,

-against-

AFFIRMATION
1:16-CV-11
(GLS/CFH)

THE UNITED STATES OF AMERICA,
NANCY A. CAFFREY, R.P.A.-C, MOSES-LUDINGTON
HOSPITAL and INTER-LAKES HEALTH, INC.

Defendants

Alan C. Heffner, MD a physician duly licensed to practice medicine in the State of North Carolina, swears under penalty of perjury pursuant to Federal Rule of Evidence 603 as follows:

1. I am a board-certified Emergency Medicine and Critical Care physician and am Co-Director of Critical Care Services at Carolinas Medical Center in Charlotte, North Carolina.

2. I submit this Affirmation in support of moving defendants' motion pursuant FRCP 56 seeking Summary Judgment dismissing plaintiff Second Amended Complaint with prejudice and on the merits.

3. I received my medical degree from Medical College of Virginia in 1997 and completed my residency in in Emergency Medicine at Carolinas Medical Center in 2000. I then completed a fellowship in Multidisciplinary Critical Care at the University of Pittsburgh Medical Center in 2007. I currently practice in the field of Emergency Medicine and Critical Care Services and am a Professor of Internal Medicine and Emergency

Medicine at Carolinas Medical Center in Charlotte, North Carolina. I am board certified by the American Board of Emergency Medicine and hold a Critical Care Medicine Certification from the American Board of Emergency Medicine.

4. I am the author of the chapters *The Unstable Patient: Optimization for Emergency Airway Management; Anesthesia and Sedation for Awake Intubation; and Flexible Endoscopic Intubation* in the Manual of Emergency Airway Management; 5'" Edition and am a national Course Instructor and Lecturer for the Difficult Airway Course™. This course is a well-recognized, advanced course designed for emergency physicians, intensivists, and hospitalists who are responsible for emergency airway management.

5. As part of my practice in Emergency Medicine and Critical Care Medicine, I have been involved in numerous situations involving acute airway management of adults, including adults with epiglottitis. I have also performed rapid sequence intubation and cricothyrotomies in the course of my practice. My qualifications are more fully described in my CV (attached hereto as Exhibit "A" and made a part hereof).

6. I have been disclosed as an expert in the field of Emergency Medicine and prepared a report pursuant to Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure. A copy of my report is attached hereto as Exhibit "B" and made a part hereof. In preparing my report and this affirmation, I have reviewed the pleadings in this case, deposition transcripts of all parties in this case, the plaintiff's medical records, the expert report of plaintiff's expert, Dr. David Bachman, and the expert deposition of Dr. Bachman. All opinions in my report and in this affirmation are given to a reasonable degree of medical certainty.

7. Based upon my review of these materials, as well as my extensive education, training, and experience in Emergency Medicine and airway management, it

is my opinion to a reasonable degree of medical certainty, that the care and treatment rendered to the plaintiff by Nancy Caffrey, RPA-C, Moses-Ludington Hospital and Inter Lakes Health, Inc. met the standard of care for a physician assistant practicing in emergency medicine and that their actions did not depart or deviate from the standard of good medical care or cause injury to Deborah Breitenbach or the plaintiff.

8. At all relevant times, Moses-Ludington Hospital was a rural 15-bed Critical Access Hospital. A Critical Access Hospital is a rural hospital that is part of a Federal program to ensure emergency services are available in isolated rural areas. Critical Access Hospitals do not have the same staffing requirements as other hospitals. They must offer 24/7 emergency care and have a physician on-call available to be on-site within 60 minutes. As a Critical Access Hospital, Moses Ludington Hospital did not have surgeons on staff or specialists available for on-site consultations.

MEDICAL HISTORY

9. As more fully discussed in my report, the records in this case indicate that the patient, Deborah Breitenbach, first presented to Moses Ludington Hospital Emergency Department at 8:55 am on 4/21/2014 with the chief complaint of "aspirin stuck in throat". She was evaluated by Nancy A. Caffrey, RPA-C at 9 :05 am who performed a history and physical exam. The record details an absence of respiratory symptoms or signs, normal pharynx voice and swallowing, and no cervical adenopathy or distress. Mrs. Breitenbach was discharged t 09:21 am with the diagnosis of esophageal foreign body sensation and was instructed to seek medical attention if her symptoms worsened.

10. The treatment provided by Nancy Caffrey, RPA-c at this first emergency room visit fully complied with accepted standards of medical care for a physician assistant

and caused no harm to the plaintiff. Indeed, the plaintiff's expert conceded during his deposition that there were no deviations during this first emergency room visit.

11. At 2:37 pm that afternoon, Mr. Breitenbach called the Porter Internal Medicine Clinic in Middlebury, VT as his wife's symptoms were worsening. After speaking with Dr. Naomi Hodde, Margaret Thompson, LPN, arranged for the patient to be seen on follow-up on the morning of April 22, 2014.

12. Mrs. Breitenbach's symptoms, however, continued to worsen, and plaintiff drove her to Ticonderoga Health Center several hours later arriving at approximately 7:28 pm. At Ticonderoga Health Center, Mrs. Breitenbach's chief complaint was of sore throat and headache. She reported throat pain and swelling, difficulty breathing and swallowing, and fever and chills. Her exam at Ticonderoga Health Center demonstrated moderate distress, tachycardia, stridor, left face and neck swelling, and difficulty breathing. Mrs. Breitenbach was then referred to the Moses Ludington Emergency Department for further evaluation, arriving there by private vehicle at 7:41 pm.

13. Nancy Caffrey, RPA-c, who was still on duty in the Emergency Department, promptly reassessed Ms. Breitenbach, suspected epiglottitis based on her clinical presentation, and ordered a stat soft tissue neck radiograph. This study was performed at 8:12 pm and confirmed the clinical diagnosis of epiglottitis. Ms. Caffrey appropriately ordered IV antibiotics and at approximately 8:15 pm, called Dr. Hubbell, an otolaryngology specialist (ENT) at Fletcher Allen in Burlington, VT, who accepted the patient for immediate transfer.

14. A call was also placed at this time to the regional EMS dispatch with a request for helicopter transfer. The Dispatch informed the Moses Ludington staff that it would be at least 55 minutes before a helicopter could arrive. It was then decided to use

the local Advanced Life Support ambulance for the transfer. A Lamoille Ambulance Service crew was dispatched to Moses-Ludington Emergency Department for inter-facility transport of the patient at 8:36 pm. They arrived at 8:46 pm and remained on scene until Mrs. Breitenbach was transferred to Fletcher Allen at 11:00 pm.

15. Continued evaluations of Mrs. Breitenbach identified deteriorating status, marked by stridor and increased difficulty breathing. Transfer without airway management was deemed dangerous and Ms. Caffrey contacted her supervising physician, Dr. Toni Sturm, who evaluated the patient 8:45 pm. Dr. Sturm further discussed the case with Dr. Hubbell and they agreed on the priority to secure the patient's airway prior to inter-facility transport. An airway management plan was devised and discussed with Dr. Hubbell prior to intervention which commenced at approximately 9:08 pm. Transport by any means at this point was not possible without first securing a stable airway for the patient. Recognizing the difficult airway situation, Ms. Caffrey and Dr. Sturm discussed and prepared for a multi-tiered airway management stategy, that included back up surgical airway instrumentation.

16. Efforts at airway management were formally initiated at 9:08 pm with administration of nebulized lidocaine to facilitate an awake intubation. The patient was unable to tolerate an awake intubation. It was then decided to administer a sedative agent along with a paralytic and then reattempt oral intubation (RSI). These agents were given intravenously at 9:23 pm. When Ms. Caffrey again attempted intubation, she was unable to visualize successfully the vocal cords, with the anatomy obscured by "massive redundant red inflamed tissue" and the epiglottis not readily discernible. She did try to pass an endotracheal tube, but was unsuccessful with the tube determined to be in esophagus rather than in the trachea.

17. Once it was evident that a surgical airway would be required, this was immediately undertaken at 9:34 pm via needle cricothyrotomy and then an open surgical cricothyrotomy. Rescue needle cricothyrotomy failed to provide adequate ventilation. Open surgical cricothyrotomy was undertaken with difficult placement of the endotracheal tube.

18. The patient deteriorated to cardiac arrest during attempts to secure the airway. Ultimately, open surgical cricothyrotomy was successful via passage of a 3-0 endotracheal tube. The patient was resuscitated from cardiac arrest. Ambulance personnel assisted with resuscitation. Post Intubation management provided by PA Caffrev and Dr. Sturm included securing the airway, surgical site hermostasis, management of hemodynamics, and initiation of therapeutic cooling.

19. Lamoille Ambulance Service left Moses-Ludington Emergency Department with the patient at 11:00 pm with Dr. Sturm on board and arrived at Fletcher Allen Health Care Emergency Department at 11:55 pm. During this transport, the records indicate the patient was well oxygenated.

20. When the patient arrived at Fletcher Allen her oxygen saturation was 99% which is evidence that her airway was well-maintained and she was well oxygenated during the transport.

21. Once at Fletcher Allen, an ENT resident was unable to intubate the patient and was unable to pass a bougie (a thin, flexible device that can be used to assist in a difficult intubation). Eventually, an anesthesiologist was called who performed an orotracheal intubation with the assistance of an airway bougie.

22. Multiple exams confirmed the patient suffered anoxic brain injury. Life support was withdrawn and Mrs. Breitenbach expired on 4/22/14.

23. Based upon my review of the records and deposition testimony, it is my opinion, within a reasonable degree of medical certainty, that the care rendered to Deborah Breitenbach by the defendants at Moses-Ludington Hospital met or exceeded the acceptable standards of care for the practice of emergency medicine in all respects. Standard of care during the second patient encounter required recognition of the emergency condition of upper airway compromise and management of this condition. Standard of care for the management of the rapidly evolving upper airway obstruction required recognition of a difficult airway situation and use of an organized airway management plan.

24. Patient management during the return emergency department encounter was correct and appropriate for the patient's clinical condition and available resources. Specifically: PA Caffey quickly recognized the patient's acuity and suspected epiglottitis. Confirmatory diagnostic studies and initial treatment with intravenous fluids, antibiotics and steroids were timely and appropriate.

25. In reviewing Dr. Bachman's deposition transcript, he criticizes the defendants over the means of transport ordered and their approach to the airway management.

MEANS OF TRANSPORT

26. Consultation with the nearest off-site ENT specialist, with anticipation of transfer was timely and appropriate. The decision regarding the type of transport used is a medical judgment. In this case, the decision to use land transport (ambulance) met the standard of case as the ambulance was readily available and a helicopter could not even be at Moses-Ludington for at least 55 minutes. Had the patient not unexpectedly decompensated, land transport was the quickest way to get the patient to Fletcher Allen.

Even if the helicopter had been called and arrived at Moses-Ludington within about an hour of the time the ambulance was called, air transport would not have been an option when the helicopter arrived because the patient did not have a stable airway.

27. Dr. Bachman opines that had a helicopter been called a helicopter would have provided an experienced flight crew with advanced airway skills. There is nothing in the medical records or witness testimony to support this opinion. In his deposition testimony, Dr. Bachman admitted that this was an assumption on his part and that he has no knowledge of the helicopter transport service available to Moses-Ludington on that date and at that time.

28. Even if a flight crew "with advanced airway skills" could have arrived at Moses-Ludington in time to assist with securing this patient's airway, it is pure speculation to assume a better outcome for this situation and patient. Once at Fletcher Allen, even an ENT resident was unable to intubate the patient and in the absence of time constraints to complete the procedure.

AIRWAY MANAGEMENT

29. Ms. Caffey exhibited insight in recognizing progressive patient deterioration marked by signs of critical airway compromise and impending airway obstruction. As such, the decision to delay patient transfer and attend to the patient's, impending and life-threatening airway obstruction was prudent and exemplified good medical judgment. Real-time discussion with the off-site ENT specialist corroborated this plan and confirmed that the airway needed to be secured prior to transfer. There were no additional on-site providers with more experience to handle the situation. The team appropriately recognized the patient's clinical features and anticipated complicated upper airway anatomy and difficult airway management.

30. The team quickly developed a thoughtful airway management plan that started with awake anesthetized video laryngoscopy. Inadequate airway visualization and continued patient deterioration represented a "forced to act" scenario. Rapid sequence intubation (RSI) was undertaken to optimize laryngoscopy view with a double set-up approach incorporating preparation for emergency cricothyrotomy. The patient's anterior neck landmarks were identified and marked prior to undertaking airway management. The airway plan was executed in the anticipated sequence based on airway finding and the patient's real-time condition. Bag-valve-mask was attempted during and between airway maneuvers.

31. This plan of action including the options utilized and the order of same fully complied with the standard of care and were in accordance with the accepted Emergency Airway Algorithms that were standard of care at the time.

32. Dr. Bachman criticizes the defendants for attempting RSI and not proceeding directly to an awake cricothyrotomy. In my opinion, Dr. Bachman is not qualified to render an expert opinion on this issue. During his deposition, Dr. Bachman admitted that he has never seen a case of adult epiglottitis and has never performed a surgical cricothyrotomy, to include one in an awake patient. His most recent experience with the disease of epiglottitis was in a child in 1989. As such, he does not possess the requisite experience necessary to render expert opinions on the performance of a cricothyrotomy here or the manner it was performed by the defendants.

33. It was appropriate and within the standard of care for the defendants to attempt RSI on this patient. The majority of adult patients, even with a recognized difficult airway, can be managed using RSI. The use of a fast acting and short-lasting paralytic is the standard of care when RSI is attempted. In this circumstance, RSI can provide the

best chance to quickly secure a patient's airway. In this case, Dr. Sturm had experience performing RSI procedures in an emergency room setting and it was reasonable medical judgment for the team to attempt RSI in this case context and prior to cricothyrotomy.

34. In accordance with the plan, cricothyrotomy was attempted following the unsuccessful laryngoscopy and thirteen minutes before the patient went into cardiac arrest. The high risk of patient deterioration during airway management was recognized *a priori*. Patient deterioration, including cardiac arrest, does not represent a deficiency in medical decision making, preparation or technical proficiency. Rather, the management of this rare and rapidly evolving emergency illustrate a thoughtful and deliberate strategy and plan execution.

35. Timely and appropriate post-intubation and post-cardiac arrest care was provided including cardiopulmonary support and therapeutic cooling and further exemplifies detailed attention to this critical patient.

36. Even if Dr. Bachman were qualified to give an opinion on the cricothyrotomy that was performed in this case, his remaining criticisms do not amount to deviations from the standard of care.

37. Dr. Bachman opinions that it was a deviation for the defendants not to use a bougie during the cricothyrotomy. Although use of a bougie is becoming more common today, it was not the standard of care in 2014. The *Walls Emergency Airway Management Manual* is a well-recognized reference on emergency airway management. The 2012 4th Edition of the Manual makes no mention of the use of a bougie during cricothyrotomy.

38. Even if use of a bougie was standard of care, Dr. Bachman has no basis to opine that 1) a bougie was available in the Moses-Ludington Hospital Emergency Room or 2) that the use of a bougie would have led to a different outcome in this case. In fact,

the records indicate that an ENT resident at Fletcher Allen attempted to intubate the patient with the aid of a bougie and was still unsuccessful.

39. Finally, Dr. Bachman claims that the defendants deviated in making a vertical incision in the cartilage when performing the cricothyrotomy. He bases this on a brief note from the autopsy report that there was a vertical incision in the anterior aspect of the trachea. Both Dr. Sturm and PA Caffrey testified that an initial, deep vertical skin incision was followed by a horizontal incision through the cricothyroid membrane, as it typical. There is no indication in the autopsy report as to whether the vertical trachea defect stems from the first incision, the second incision, or a consequence of tracheal manipulation during or after the procedure. As such, this autopsy report does not establish a deviation in how the cricothyrotomy was performed. The difficulty that the defendants encountered in placing the tracheal tube following tracheal incision is also well recognized and does not represent a deviation from the standard of care.

40. Based on the above, it is my opinion to a reasonable degree of medical certainty that the care and treatment rendered by PA Caffrey, Moses-Ludington Hospital and Inter Lakes Health, Inc. to Deborah Breitenbach from an Emergency Medicine standard, fully met, adhered with and exceeded the standard of care and did not cause any injury or damage to the Deborah Breitenbach or the plaintiff.

41. All the opinions I have expressed in this affirmation and made to a reasonable degree of medical certainty.

DATED: February 11, 2018

2.11.18

ALAN C. HEFFNER, M.D.